DEC 1 2 2000

K003660

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:
LEIBINGER® Neuro Clip System

General Information

Proprietary Name:	LEIBINGER® Neuro Clip System
Common Name:	Neuro Clip/Fixation Pin Smooth or Treaded Metallic Bone Fixation Fastener 21 CFR 888.3040, Class II Neuro Clip Implant Applicator/Pistol Orthopedic manual surgical instrument 21 CFR 888.4540, Class I exempt
Proposed Regulatory Class:	Class II
Device Classification:	87 HTY (bone fixation) 87 LXH (manual surgical instrument)
Submitter:	Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 800-253-7370
Submitter's Registration #:	1811755
Manufacturer's Registration #:	8010177
Contact Person:	Robin L. Rowe Regulatory Affairs Associate Telephone: 616-323-7700 x3295 Fax: 616-324-5412
Summary Preparation Date:	November 22, 2000

Intended Use

The subject device, LEIBINGER® Neuro Clip System, is for fixation of the cranial bone flap. It is our intention to make this device available for fixation of craniofacial bone flaps with the use of currently marketed bone screws, such as, but not limited to the (K854886) Würzburg Titanium Mini System. The intended use for the LEIBINGER® Neuro Clip System has not changed from the Spetzler Pin (K945639 and K954001 cleared by the FDA), although data does not support the mixing of Ti-6Al-4V with grade 5 Titanium in the same surgical field. See Appendix C for equivalency.

Device Description

The Stryker LEIBINGER® Neuro Clip is intended for fixation of the cranial bone flap to the surrounding cranium after a craniotomy procedure. A minimum of four LEIBINGER® Neuro Clips are recommended for fixation. The lower single pin is inserted into the diploe of the cranial bone with the implant applicator/pistol accessory rather than a pin holder and riveting mallet as described in the Spetzler Pin. Additional plating or mesh is not necessary with the LEIBINGER® Neuro Clip to aid in fixation of the cranial bone flap. The LEIBINGER® Neuro Clip has a single pin design, which is parallel to the plate, which is placed on the anterior cranium. A countersunk hole in the plate is available to secure a currently marketed 1.7mm -1.9mm commercially pure Titanium or Titanium Alloy Bone Screw to provide stability and protection against sinking of the flap. The LEIBINGER® Neuro Clip has been manufactured with a low profile to decrease any device prominence.

Substantial Equivalence

EQUIVALENT PRODUCTS:

The Leibinger® Neuro Clip System is substantially equivalent to already legally marketed devices in commercial distribution. Examples of these devices is listed below and additional literature is included in Appendix C.

Spetzler Pin K945639 and K954001– Submitted by the former Howmedica, Inc (refer to, Administrative Information, Submission Purpose for Stryker Leibinger acquisition of product lines).

Robin L. Rowe
Regulatory Affairs Associate
November 22,2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2000

Ms. Robin L. Rowe
Regulatory Affairs Associate
Stryker Instruments
Leibinger Division
4100 East Milham Avenue
Kalamazoo, Michigan 49001-6197

Re: K003660
Trade Name: Liebinger Neuro Clip System
Regulatory Class: II
Product Code: JEY
Dated: November 22, 2000
Received: November 28, 2000

Dear Ms. Rowe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003660

510(k) Number (if known):_____

Device Name: LEIBINGER® Neuro Clip

Indication For Use:

The Stryker LEIBINGER® Neuro Clip

The subject device, LEIBINGER® Neuro Clip System, is for fixation of the cranial bone flap in non-load barring areas. It is our intention to make this device available for fixation of craniofacial bone flaps with the use of currently marketed bone screws, such as, but not limited to the (K854886) Würzburg Titanium Mini System. The intended use for the LEIBINGER® Neuro Clip System has not changed from the Spetzler Pin (K945639 and K954001 cleared by the FDA), although data does not support the mixing of Ti-6Al-4V with grade 5 Titanium in the same surgical field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH,Office of device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use_____
(per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003660